# Australia: Analytical and Clinical Chemistry Industry

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## Summary

Australia has an ageing population of 20 million people, a high per capita income, and a high standard of medical practice. Together with the expectation of state-of-the-art medical treatment by an educated population, there is a demand for innovative medical products. Approximately 90 percent of medical devices and diagnostics used in Australia are imports. The United States is the major supplier of medical products, followed by the European Union.

Pathology testing plays a critical role in the diagnosis and monitoring of illness and medical treatments in Australia. It accounts for approximately US$1.3 billion of the Australian annual healthcare budget. While the ageing of the population has a significant impact on the number and type of health care services delivered, there has been a significant increase in pathology test ordering rates by General Practitioners (GPs). With the increasing emphasis on prevention and management of chronic disease, there will continue to be an increase in pathology ordering by GPs.

## Market Demand

Australia has a government-funded healthcare system. National expenditure on health is 8.8 percent of GDP. Australia's expenditure on healthcare to GDP ratio is comparable to Italy (8.9 percent) and Canada (9.8 percent), slightly more than the United Kingdom (8.3 percent), but considerably less than the United States (15.3 percent).

The Australian health system is complex with many types of service providers and a variety of funding mechanisms. The Australian government (federal and state governments) funds approximately 68 percent of total health expenditure.

A significant portion of the Australian government's health expenditure is to provide funding to promote the quality and effectiveness of pathology services to ensure that Australians receive the services that they require for their health management. The Medicare Benefits Schedule, one of the government's major national subsidy schemes, pays for medical services performed by pathologists. The Australian government funds over 92 percent (or US$1.3 billion dollars a year) to support pathology services under the Medicare Benefits Schedule.

The pathology services industry in Australia provides a range of testing and analysis services for the medical professions, public and private hospitals, and other healthcare organizations. The major services that this industry provides include biochemistry, anatomical pathology, hematology, microbiology, immunology, and cytopathology. The major customer base comprises doctors and hospitals. Other customers include community health centers, dental practices, and veterinary clinics.

The number of pathology tests ordered by GPs continues to rise. GPs are ordering an average of two tests per problem tested, and the number of chemical pathology and hematology tests ordered is increasing. These increases are reflected in pathology ordered for diagnostic and preventive care, and to a lesser extent in monitoring pathology. The Australian Institute of Health and Welfare reports that, in 2006-2007, the proportion of encounters generating pathology test orders increased by 44 percent compared to 2000-2001.

The most common pathology tests ordered are chemistry (58 percent of all pathology tests), hematology (19 percent) and microbiology (14 percent). Many factors have contributed to the increase in pathology test ordering rates by GPs. These include an increase in management rates of chronic diseases such as diabetes and increases in the number of people taking medications (for example lipid lowering agents). Other influential factors include: a greater availability of tests; increased patient expectations; more knowledgeable patients; and the fear of litigation by medical practitioners.

## Market Data

Australians generally enjoy good health and have a range of healthcare services available to them. Overall, Australians enjoy one of the highest life expectancies in the world. Australia ranks in the top five nations for life expectancy rates and is comparable to Japan, Iceland, Sweden, and Switzerland, and higher than the United States and the United Kingdom. The life expectancy for males is 78 years and for females is 83 years.

There are 450 pathology laboratories in Australia employing 11,300 people. The industry's total turnover is approximately US$2 billion. Private pathology operators conduct most pathology testing. The structure of the industry is moving from a large number of "small player" partnership-based professional practices to a few larger corporate pathology services firms.

In 2006-2007, the problems for which pathology was most frequently ordered were:

Diabetes
Hypertension
Lipid disorders
General check-up
Female genital check-up
Weakness/tiredness general
Urinary tract infection
Pregnancy

## Best Prospects

Drivers for growth for particular tests include the health and demographics of the population. Similar to the United States, Australia is experiencing an ageing population. Growth in the demand for pathology services is expected to continue as the "baby boomer" generation ages, particularly as its members move into their seventies. The elderly are large users of pathology and most of their conditions can only be diagnosed through blood tests. As the range of diagnostic services available increases, so does the demand for these services.

The leading causes of death include cardiovascular disease and cancer. The Australian government has identified seven national health priority areas that pose a significant burden of disease:

Asthma
Cancer control (lung, colorectal, melanoma, prostate, breast, cervical, and non-Hodgkin's lymphoma)
Cardiovascular health
Diabetes
Injury prevention and control
Mental health
Arthritis and musculoskeletal conditions

The more common problems managed in general practice that have seen a significant increase in pathology testing includes: cardiac check-up, hypertension, menopausal problems, diabetes, and ischaemic heart disease.

The industry is continually increasing its use of advanced technologies to speed up delivery of service to its customers and to produce cost efficiencies. Growth markets that are not funded by the government through Medicare, include occupational tests, sports drug tests, and clinical trial tests.

## Key Suppliers

The market for clinical laboratory and diagnostic instruments is mature. Competitive, innovative products, pricing, and quality are key factors for success.

The Australian government commissioned a study into the in vitro diagnostics (IVD) industry in 2003. Results of the study revealed that more than 95 percent of IVDs were imported and less than 5 percent were locally manufactured. Additionally, suppliers of IVDs reported that less than 5 percent of their IVD sales came from home use IVD products. Most importers reported their source of IVDs to be either the United States or the European Union.

## Prospective Buyers

There is a trend towards corporatization in the pathology industry. The Australian pathology industry has undergone significant structural change and is dominated by a small number of large corporate providers. The two largest pathology companies account for approximately 74 percent of the pathology market. These companies typically operate central laboratories and have a network of collection centers. In addition to consolidation, there is a continuing trend towards vertical integration of pathology providers with private hospital providers. Some hospitals are contracting private pathology providers for the provision of pathology services.

The major customer-base of pathology practices is comprised of referring doctors (70%) and hospitals (20%). Many Australian doctors and scientists have spent some time studying in the United States and are familiar with American products.

## Market Entry

The Australian Therapeutic Goods Administration (TGA) regulates medical devices and IVDs. Australia's regulatory framework for medical devices is based on Global Harmonization Task Force (GHTF) and European Community (EC) guidelines. All IVDs need to conform to Essential Principles for quality, safety, and performance. IVDs are classified into four classes, based on risk, with levels of regulatory oversight commensurate with the risk posed. The TGA is in the process of formulating a new regulatory framework for IVD's. Currently, IVDs requiring TGA approval include those for: home use, diagnosis of HIV and HCV, and IVDs that contain human origin material.

IVDs requiring approval have to be entered on the Australian Register of Therapeutic Goods (ARTG) as a basis for approval to supply in Australia. Applications for entry on the ARTG must be lodged by an Australian-based Sponsor that accepts responsibility for the goods in Australia.

Further information on Australia's regulatory system for IVDs can be can be obtained from the TGA's website: **http://www.tga.gov.au/devices/ivd.htm#current**

Under the U.S. - Australia Free Trade Agreement, medical devices continue to attract no import duty.

## Market Issues & Obstacles

Pathology services in Australia operate in a capped-funding and highly-regulated market. Pathology services are reimbursed by the Australian Department of Health and Ageing according to the Medicare Benefits Schedule. The majority of pathology tests conducted in Australia are reimbursed under Medicare, and as a result, the government endeavors to limit the excessive use of pathology services for which a Medicare benefit is payable.

Consequently, the Australian government has entered into agreements with the Australian Association of Pathology Practices and the Royal College of Pathologists of Australasia to cap pathology expenditure under Medicare benefits arrangements. The Australian government limits the growth of the government's expenditure on pathology services to five percent per annum.

Under Medicare, using "Item Test Coning," regardless of how many different tests a doctor may request for a patient, only the three most expensive tests are eligible for Medicare reimbursement. Medicare benefits are not payable in respect of a pathology service unless the service was rendered by or on behalf of an Approved Pathology Practitioner, was rendered in an Accredited Pathology Laboratory, and the proprietor of the laboratory is an Approved Pathology Authority.

The Australian Association of Pathology Practices reports that while this has been a difficult process for providers, the pathology profession has agreed to the capped funding of Medicare pathology services because it has delivered the following benefits:

- continued fee-for-service for this medical service
- certainty in outlays to the government
- agreed annual growth rates
- industry stability during a period of unprecedented consolidation and corporatization
- professional survival for pathologists and scientists
- improved efficiencies in delivery of services

However, capped funding has also created some difficulties, including:

- reduced margins in pathology practices
- a potential adverse effect on quality by requiring more for the same amount of money
- dampened entrepreneurship by limiting the return on investment
- potential to constrain growth and risk long-term sustainability

## Trade Events

Many Australian suppliers and distributors of clinical laboratory and diagnostic products attend Medica in Germany, and the annual American Association for Clinical Chemistry (AACC) and the American Society for Microbiology conferences in the United States.

## Resources & Contacts

Department of Health and Ageing
www.health.gov.au

Therapeutic Goods Administration (TGA)
Website: www.tga.gov.au

## For More Information

The U.S. Commercial Service in Sydney, Australia can be contacted via e-mail at: Monique.Roos@mail.doc.gov; Phone: +61 2 9373 9210; Fax: +61 2 9221 0573; or visit our website: www.buyusa.gov/australia.

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